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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/467,368	12/20/1999	PETER KAMP HANSEN	4324.224-US	2312

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EXAMINER

RAO, MANJUNATH N

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 05/07/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/467,368

Applicant(s)

HANSEN ET AL.

Examiner

Manjunath N Rao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1-7-02 has been entered.

New claims 30-53 are now pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a xylanase from *Thermomyces lanuginosus* (also known as *Humicola lanuginosus*) strain DSM 4109, with amino acid sequence SEQ ID NO:2, does not reasonably provide enablement for any xylanase enzyme having a pH optimum in the range of 4.5-7.5 and a residual activity after incubation for 60 min at pH 6.0 selected from one or more of a) >96% residual activity when measured at 60 degree C, b) >83% residual activity when measured at 65 degree C, c) >20% residual activity when measured at 70 degree C, d) >10% residual activity when measured at 75 degree C, as recited in claim 30, from any source including natural or recombinant, plants, animals, microorganisms such as any bacteria, fungi, thermophilic fungi or yeasts etc. The specification does not enable any person skilled in the art

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to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 30, 37-40 are so broad as to encompass any xylanase enzyme from any natural or recombinant source having a pH optimum of 4.5-7.5 and a stability as defined in claim 30, while claims 31-36 each are restricted to xylanase with such properties from a variety of thermophilic fungi. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of xylanase enzymes broadly encompassed by the claims. Since the amino acid sequence of a protein and extent of purity of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and to obtain the desired activity, requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to a single xylanase enzyme isolated *Thermomyces lanuginosus* without any of the above information.

While enzyme isolation techniques and recombinant techniques are known, it is not routine in the art to screen multiple sources, as encompassed by the instant claims, and the reasonable expectation of success in obtaining the desired enzyme are limited due to the complexity of the huge number of sources that need to be analyzed and the result of such isolation from an extremely large number of sources is unpredictable.

The specification does not support the broad scope of the claims which encompass all xylanase enzymes from any source because the specification does not establish: (A) a rational

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and predictable scheme for isolation and characterization of any xylanase from any given source with an expectation of obtaining the desired biological activity and function; (B) the specification provides insufficient guidance as to which of the infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any xylanase enzyme isolated from any source. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claims 30-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 30-40 are directed to xylanase derived from a thermophilic fungus, with a pH optimum in the range of 4.5-7.5 and a residual activity after incubation for 60 min at pH 6.0 selected from one or more of a) >96% residual activity when measured at 60 C, b) >83% activity when measured at 65 C, >20% activity when measured at 70 C and > 10% activity when measured at 75 C, wherein such an enzyme is used in animal feed. Claims 30-40 are rejected under this section of 35 USC 112 because the claims are directed to a genus of natural or

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recombinant polypeptides including modified polypeptide sequences, modified by at least one of deletion, addition, insertion and substitution of an amino acid residue in a xylanase amino acid sequence and fragments of same that have not been disclosed in the specification. No description has been provided of all or even a representative number of polypeptide sequences encompassed by the claim. No information, beyond the characterization of SEQ ID NO:2 has been provided by applicants which would indicate that they had possession of the claimed genus of polypeptides. The specification does not contain any disclosure of the structure of all the polypeptide sequences derived from SEQ ID NO:2, including fragments and variants within the scope of the claimed genus. The genus of polypeptides claimed is a large variable genus including peptides which can have a wide variety of structures. Therefore many structurally unrelated polypeptides are encompassed within the scope of these claims. The specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102/103 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 30-53 are rejected under 35 U.S.C. 102(b) as anticipated by Lischnig et al. (Biotechnology letters, 1993, Vol. 15(4):411-414) or Gomes et al. (Appl. Microbiol. Biotechnol., 1993, Vol. 39:700-707) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lischnig et al. or Gomes et al. and Alam et al. (Enzyme Microb. Technol., 1994, Vol. 16, pages 298-302). This rejection is based on the public availability of printed document regarding xylanase enzyme.

Claims 30-40 of the instant application are drawn to a xylanase enzyme isolated from *Humicola lanuginosa* which has a pH optimum in the range of 4.5-7.5 with a residual activity as disclosed in claim 30 and its use as an animal feed additive. According to applicants own admission, the xylanase enzyme of *Humicola lanuginosa* was known in the prior art as preparations described by Lischnig et al. or Gomes et al. (See page 1, line 28-33) and its use in animal feed (Alam et al. page 2, lines 5-11 of the specification) . Therefore the xylanase enzyme of the instant application anticipates the xylanase enzyme of the reference. Even if applicants argue that the enzyme of the reference was not a monocomponent xylanase and was a crude mixture, it would be obvious for one skilled in the art to use the knowledge existing in the field of enzyme purification, and recombinant techniques at the time the application was filed,

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and purify the xylanase to homogeneity and claim it and use it for making an animal feed (claims 30-40) or make recombinant DNA and isolate the encoded xylanase from polynucleotides that hybridize to said recombinant DNA under the highly stringent conditions and use it for making an animal feed as in claims 41-53. Thus Lischnig et al. or Gomes et al. and Alam et al. anticipates claims 30-53 or make them *prima facie* obvious as written.

Applicants may argue that claims 41-53 are drawn to xylanases that are encoded by polynucleotides which hybridize to nucleotides 31-705 of SEQ ID NO:1 and the references provided by the Examiner fails to provide such sequences. Such an argument would not be persuasive to overcome the rejection because, based on the characteristics of the enzyme in the reference and the instant xylanase, Examiner takes the position that the enzyme in the reference and the instant enzyme are one and the same and the amino acid sequences and polynucleotide sequences that encode them are inherent characteristics. Since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594. Furthermore, the decisions handed down in *In re Bell* and *In re Deuel* also does not apply to the above situation. This is because applicants are not claiming polynucleotides encoding the xylanase in which case a reference showing the purified protein would not have rendered the DNA obvious (provided applicants had provided a SEQ ID NO for the polynucleotide). However, in the instant case

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applicants are claiming the polypeptide and the decisions of *In re Bell* and *In re Deuel* does not apply.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 30-53 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 7-17 of U.S. Patent No. 6,245,546 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the same xylanase enzyme encoded by the same polynucleotide (nucleotides 31-705 of SEQ ID NO:1) and a premix and a process of making animal feed comprising the above xylanase enzyme.

Conclusion

No claims are allowed.

This is a CPA of applicant's earlier Application No. 09/467,368. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier

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application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

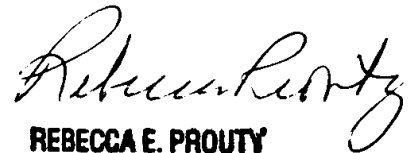
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath Rao whose telephone number is (703) 306-5681. The Examiner can normally be reached on M-F from 6:30 a.m. to 3:00 p.m. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, P.Achutamurthy, can be reached on (703) 308-3804. The fax number for Official Papers to Technology Center 1600 is (703) 305-3014.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



**REBECCA E. PROUTY
PRIMARY EXAMINER**

GROUP 1800

1600

Manjunath N. Rao

5/2/02